Exhibit C

Deposition of:

Rebecca Betensky , Ph.D.

June 23, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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literature. So, so I would expand it in that way.

Q I think that's helpful. We're going to get to this at a little bit later because I think it's important to delineate the topics that you have expertise in to the topics that you obviously are going to say that's for somebody else, okay.

For example, you're not an engineer, right?

A I'm not an engineer.

Q Right. So for the purpose of my question, I think you might understand what I'm driving at a little bit better, in this case you're employing your expertise in the field of biostatistics and the application of statistics to various data sets; is that right?

MR. MANKOFF: Object to form.

A I think it's broader than that. I -- again, I'll -- I would like to emphasize that I have, you know, 25 years of experience as a Ph.D.-level statistician who has collaborated extensively with investigators in the medical field, and so I have quite a bit of expertise in the application of statistics to medicine, to medical studies, to epidemiological studies.

Q Understood. And you raise a good point.

When I took a look at your CV, you had many,

many articles in the world's published literature, right?

A I'm sorry, in the what?

Q There are many articles listed in your CV where you've collaborated with experts in the field of medicine in various disciplines, right?

MR. MANKOFF: Object to form.

THE WITNESS: Can you repeat that, please.

Q You've published numerous times, right?

A Yes.

Q Many, many times, right?

MR. MANKOFF: Object to form.

A Many -- if many, many -- by many, many you mean about 200, plus or minus, then yes.

Q You often collaborate with subject matter experts in various fields of medicine when you publish an article, right?

MR. MANKOFF: Object to form.

A I -- yes, many of my publi -- many of my publications are collaborative publications with experts in medicine and science.

Q For example, I've noticed on your CV various publications relating to aspects of the care and treatment of cancer patients, right?

A Care and treatment. I have some cancer-related publications. Many of them are lab related or technologic -- technol -- genetic- or genomic-related kinds of publications in cancer. Some of them are -- a few of them may be treatment related.

Q I've seen publications related to issues in the field of nephrology, right?

A Yes.

Q In those publications you are a coauthor along with various medical doctors who are experts in the underlying medicine in the article that you're writing about, right?

A Correct.

Q And that's totally routine for you is what I'm driving at, right?

A I've, I've done it regularly over many years, yes.

Q It's common practice for a statistician and a biostatistician like yourself to collaborate with subject matter experts in the various medical fields in which they're publishing. It's routine, right?

A I'm sorry if this is overly picky, but it's -- there are many statisticians who don't collaborate at all in the medical field or don't collaborate at all because they're purely theoretical.

of biostatistics, it is relatively common in your experience for biostatisticians like yourself to collaborate with medical doctors who are experts in the underlying medical issue that is the subject of the paper, right?

MR. MANKOFF: Object to form.

A So let me rephrase your question, and you can tell me if I get this right.

I would -- I can answer that and say within my department of biostatistics at the Harvard Chan School of Public Health, my colleagues, other faculty within that department and myself commonly collaborate with medical and public health and basic science experts in the development of both statistical methodology and in collaborative research, and everyone is usually an author -- a coauthor on the paper that comes out of that.

Q Totally on the same page now. I understand.

Here's the question. In your department at Harvard it is common and routine for you to collaborate with various public health experts, experts in the underlying medicine on whatever research it is you are doing, and ultimately, you will all be coauthors on whatever paper you were writing, right?

MR. MANKOFF: Object to form.

A I do that activity frequently.
Q Did you collaborate with anybody in order to create the opinions that you're proffering in this case?
MR. MANKOFF: Object to form.
A I'm sorry. What do you mean by collaborate with anybody?
Q Did you work with any other person, other than an attorney, in order to create the opinions that you've offered in this case?
A No, I did not.
Q Let's take a look to see what else we have in this folder. I have -- where are we? We've marked Exhibit No. 3?
You've also provided us a list of -- an updated list of cases where you have testified, right?
A Yeah.
Q What period of time does this list cover?
A May I see the list, please.
Q Absolutely.
MR. BUSMAN: I'm going to mark it as Exhibit 4.
(Exhibit 4 marked for identification)
A So this goes back to 2013 which I believe --

these filters are actually removed if necessary, right?
A Other than knowing that some of them at least have a hook that is used for the removal, retrieval.
Q You have no understanding of how an IVC filter could be damaged during the course of a retrieval, do you?
A No.
Q You're not an expert in the manner in which potential filter adverse events are detected, are you?
A Not in how they are clinically detected.
Q You're not a -- strike that.
You're not an expert in the differences in how adverse events are clinically detected in retrievable filters versus permanent filters, right?
A Correct.
Q You don't hold yourself out as having any expertise in the percentage of filter adverse events that are detected only upon filter removal, right?
A Again, as I mentioned, this does touch upon work that I've done in a non-Bard case.
Q Okay. Let me make that distinction.
In this litigation you're not holding yourself out as having any expertise in the percentage of filter adverse events that are first detected during the process of filter removal, right?

A Correct.
Q You're not an expert in the process by which a device company would report an adverse event to MAUDE, are you?
A I'm not sure what you mean by an expert in that. I understand that a company is required to report to MAUDE.
Q Do you hold yourself out as an expert in the FDA rules, regulations, and guidance related to submitting adverse event reports to MAUDE?
A I'm not an expert in those regulations.
Q Let's make it easy.
You don't hold yourself out as an FDA regulatory expert, do you?
A If -- I -- if there is a, such a thing as an FDA regulatory expert, I am not that.
Q Now, in this case you analyzed adverse events and compared -- strike that.
In this case you derived a reporting risk ratio comparing the number of adverse events reported to MAUDE for the Simon Nitinol filter versus the number of reports to MAUDE for the various retrievable filters we've discussed, right?
MR. MANKOFF: Object to form.
A Not exactly. So, so first of all, that

to me the assumptions that you were required to make and the purpose that you were making them for.

MR. MANKOFF: Object to form.

A So there's plenty of interpretation that can be made about a reporting risk ratio without any assumptions at all, in, in that it is a reporting risk ratio and it show -- you know, it is of a certain magnitude and -- but if, if that reporting risk ratio, in order to go -- draw inferences about the risk ratio from the reporting risk ratio, that's where assumptions are required.

Q Got it. I hope.

The reporting risk ratio that you calculated is completely divorced from any assumptions that you later employed to make inferences about the risk ratio, right?

MR. MANKOFF: Object to form.

A No, I don't think I can say that. I mean the reporting risk ratio is a number, and along with that number has to ha -- you know, I, I would provide or I did provide an explanation of where that number comes from. So it's just a number, and it has sources of information that went into its calculation. That's the reporting risk ratio.

Q The reporting risk ratio that you --

Q Did you make any assumptions about the reporting rates in connection with your analysis in this case?

A Again, the analysis stands alone without the assumptions, and it's only going from the reporting risk ratio to the risk ratio where these essential -- where, where these assumptions would be used. Now, the magnitude of the -- these reporting rates also can be informative about the risk ratio.

Q Did you make any assumptions with respect to differential reporting between the permanent SNF filter and the various retrievable filters in order to help you provide any opinions at all in this case about the reporting risk?

A So, so one assumption is I think in my rebuttal to Dr. Thisted's I expanded upon it in that report, in that rebuttal report.

And one assumption is that, is that there may be -- is that if there is differential reporting one would expect it to be pretty constant across some of the adverse events that are similar in level of seriousness.

Q Did you consult or confer with anybody that has any medical expertise with respect to the products at issue to determine whether your assumption that the

difference in reporting for the devices would be consistent?

MR. MANKOFF: Object to form.

A It seems obvious to me that, that as long as the events are of comparable seriousness that that would follow.

MR. BUSMAN: I'm going to move to strike.

Q Did you consult with anybody that has any medical expertise with respect to the adverse events at issue to determine whether your assumptions that the differential reporting -- whether your assumptions about differential reporting hold true?

A No.

Q What, if anything, did you do in this case to definitively rule out the possibility that your calculations are not the product of differential reporting between SNF and the various retrievable filters?

A So I think I expanded upon that in my rebuttal to Dr. Thisted and -- would you like me to continue?

Q Please.

A And so, so under that assumption, which seemed very reasonable to me, and other assumptions, a

you any documents from any source reflecting adverse events for the SNF prior to 2000?

A No.

Q As we sit here today do you have any idea how many reports there may have been with respect to filter fracture for the SNF from the time it was sold in 1990 until to 2000?

A No, I don't know.

Q Do you have any idea, as we sit here today, how many reports of migration there may have been for the SNF from 2000 -- strike that.

As we sit here today do you have any idea how many reports there may have been from 1990 up to 2000 for migration with respect to the NSF -- SNF?

A I don't know that number.

Q Same for embolization?

A I don't know that number.

Q Do you know the answer with respect to any of the adverse events you considered in this case?

A I don't know the numbers of adverse events for SNF prior to 2000.

Q Now, for the various other removable filters that you considered, you utilized Bard data that you understood captured a period of time from market introduction all the way up to the end of the period

that you calculated, right?

A I believe that's true. And by removable you mean retrievable according to how we've defined it.

Q Yes.

Now, you've described something previously called the Weber effect, right?

A Correct.

Q And the shorthand version of that is that statisticians like yourself and folks who have expertise in the measurement of adverse events in the statistical sense understand that the greatest number of reports for a given product happen shortly after market introduction, right?

MR. MANKOFF: Object to form.

A I believe that can happen. It's not a necessary event that it happened, but I believe it can happen.

Q In a general sense it is understood in the statistical community that the majority of adverse reports likely occur with respect to a product shortly after it hits the market, right?

MR. MANKOFF: Object to form.

A No, I don't think that would be true because certainly some adverse events take time to happen, and so -- so I guess the Weber effect would need -- if you

Q What page?

A I'm looking at the first paragraph on page 1.

-- that I considered the Bard AE reports, and the first one was 2000 to the second quarter of 2003. And again, I'm, I'm assuming for the purposes of our conver -- of our -- of your question that that means that the AEs were not cumulative over the entire life of the product, but only began in 2000.

And so under that assumption that I don't actually have adverse events from prior to 2000, then, then that is true that I did not consider adverse events before 2000. For -- right. Yeah.

Q To the extent that you did not have adverse events for the SNF prior to 2000, you've done nothing in the expert reports you've served so far in this case to determine what impact, if any, those pre-2000 adverse event reports would have on the calculations that you've submitted in this case, true?

A I would also need to know the sales numbers prior to 2000. So I have not considered sales prior to 2000 or adverse events, as far as I know, prior to 2000.

Q Because you have not considered either adverse events reports -- strike that.

Because you have neither considered adverse

event reports prior to 2000 nor sales reports prior to 2000 for the SNF, there's nothing in any of the reports that you've served so far in this case to indicate what impact, if any, those pre-2000 adverse event reports and sales would have on the calculations that you've derived, true?

A I didn't do any analysis of pre-2000 adverse events or sales for SNF.

Q You have no idea, as we sit here today, whether or not pre-2000 adverse event reports for the SNF would indicate that there is no difference for the null value with respect to the RRRs that you calculated, right? You just don't know.

A I don't have the reporting risk ratio including SNF going back to 2 -- prior to 2000.

Q It's entirely possible that had you had adverse event data for the SNF prior to 2000 and the sales data prior to 2000 that you would not have calculated any higher RRRs for the various removal products as compared to the SNF. You just don't know, right?

A I don't know what happened before 2000 on the sales or the, the adverse events or whether that's any different from what happened after 2000.

Q Good point. Let me try to clarify that.

Because you didn't have data for adverse events for SNF prior to 2000 and you didn't have sales data for SNF prior to 2000, there's no way for you, as you sit here today, to say that if you had that data and calculated reporting risk ratios perhaps the reporting risk ratios would be greater for SNF over removable, maybe they'd be lower. You just don't know one way or another, right?

A I don't have the data so I don't know what the number would be if I had had the data. It could go -- like you said, I could get -- I could have gotten RRs that are larger than what I got. I could have gotten RRs that are smaller than what I got.

Q Now, because you didn't have adverse -- strike that.

Based on the Weber effect, it would be more likely to find the greatest number of adverse events in connection with the SNF sometime within the first ten years it was on the market, right?

MR. MANKOFF: Object to form.

A So --

THE WITNESS: I'm sorry. Can you restate that?

Q We were going -- I had asked you some questions about the Weber effect, and, and perhaps I

number of reports in connection with the SNF sometime during the period between 1990 when it hit the market and 2000 when you started your analysis?

MR. MANKOFF: Object to form.

A I do know, and I'm reading in my report right now, that although the SNF was lunched in 1990, the first death associated with it was not -- did not occur until 1997. So that's just one piece of information. But I don't know, I don't know whether the Weber effect was in play here or not.

MR. BUSMAN: Okay. I'm going to object and move to strike everything other than you don't know whether the Weber effect was in play or not.

Q As you sit here today do you know how many reports of death there were for the SNF between 1997 and 2000?

A No.

Q Now, you had Bard data reflecting reports of adverse events for every other removable filter that we've discussed starting at the time of product launch going through the end of your analysis, right?

A I believe that's what I had.

Q You've also stated in your expert report that as a general proposition there are more -- it is more likely that MAUDE will get reports of adverse events

for newer devices on the market as opposed to older devices, right?

MR. MANKOFF: Object to form.

A Again, my understanding is that this is a sys -- it's a complex system and that is -- one driver of reporting is the newness of the device, but there are other -- may be other drivers as well.

Q Let me see if I can restate that.

One driver of reporting that you understand exists for medical devices in a general sense is that newer medical devices are likely to receive more reports as recorded in MAUDE than older devices, right?

A I don't know about likely. I can't say are likely to. I can say that's a possibility.

Q Let me try it again.

You recognize that it's possible that newer devices have more MAUDE reports of adverse events than older devices, right?

A That's possible.

Q In your analysis you captured periods in which the removal devices were new to the market, right?

A Yes.

Q In your analysis you didn't start considering adverse events for the Simon Nitinol filter until it

had been on the market for over ten years, right?

A I believe that's true.

Q *You did not do an apples-to-apples comparison of time periods for any of the removable filters as compared to the analogous time periods in which the Simon Nitinol filter had been on the market, right?

MR. ROTMAN: Please reread that question.

(*Record read)

MR. MANKOFF: Object to form.

THE WITNESS: I'm sorry. Can you restate that, please.

MR. BUSMAN: Sure.

Q If you really wanted to do an accurate and meaningful comparison between various of the Recovery filters and the Simon Nitinol filter, you would have wanted to compare MAUDE reports for any of the recoverable filters in the first few years those filters had been on the market as compared to the reports for the first few years when the Simon Nitinol filter was on the market, right?

MR. MANKOFF: Object to form.

A Well, that's one analysis certainly, but I guess I'm -- or let me back up. But another way of

looking at this would be that what's of interest might -- is really the current status.

And, you know, although the SNF came on the market in 1990, perhaps other things have changed in medicine and in treatment of these patients who received these filters and in, you know, ancillary treatments or drugs that are given to them alongside it or how surgery is conducted or any number of things that might have changed from 1990 to 2000.

And so, so that would be a reason why it might be more meaningful to compare at a -- at the same time period given that medi -- you know, things in medicine do change quite a bit over ten years, and those might be important factors. And so, so it might be more meaningful to be comparing at that time.

Secondly, even if there were no change in medicine in the drugs patients are given or the way the surgery or the procedure is done or anything like that, it is of interest to compare to the current functioning SNF. So that would be I think another reason to -- why this would, would contribute useful information.

Q Do you know what, if anything, has changed in the medical practice that might impact your opinions from the ten years that were omitted from your analysis to present or are you just speculating that things have

changed?

MR. MANKOFF: Object to form.

A Well, it's -- I'm stating this based on my understanding of, of medicine through involvement in clinical trials and through, you know, my, my very -- you know, my various involvements in different kinds of medicine that things can change quite a bit over a time period in ways that really matter a lot in terms of how patients do. And that -- that's seen a lot of in clinical trials and so I wouldn't call it speculation. I would call it I'm using my experience and understanding to make that statement.

Q Do you know, as we sit here today, what specifically has changed over the ten-year period for which you don't have any information on adverse events for the Simon Nitinol filter up until when you started your analysis in 2000, do you know what has changed specifically that is reflected in your expert reports in this case?

A So that's -- I mean that's --

MR. MANKOFF: Object to form. Go ahead.

A So I'm not a clinical expert so that would be something for a clinical expert to comment on.

MR. BUSMAN: Can we go off the record for a moment, folks?

it was that you've, you've done here in this report?

MR. MANKOFF: Same objection.

A I -- as I'm looking at this now, I -- it appears that I addressed it in some part. It's not -- I wouldn't consider it, you know, a complete con -- I didn't completely address -- I didn't comprehensively address each of these. I considered what they are and, and maybe considered some possible responses to them.

Q Okay. You didn't comprehensively consider each and every limitation to the data that you analyzed in this case, you, rather, considered some of them, right?

A This is a, you know, this is a list, and I'm sure there are additional potential limitations as well.

Q Let me jump back. I forgot to ask you a question.

What was the specific hypothesis that you were analyzing this in this case?

MR. MANKOFF: Object to form.

A So the question was a com -- the hypothesis of -- or compar -- compar -- the task or the, the, the purpose was to compare a select set of adverse events between the retrievable filters and the permanent SNF filter.

Q Who provided you the hypothesis that you analyzed?

MR. MANKOFF: Object to form.

A That was the question that the attorneys asked me to address.

Q Am I correct that the attorneys didn't give you a set of data and said analyze the data and tell me whatever it is that you find through various statistical models, but, rather, asked you to analyze and confirm a hypothesis that they had already determined?

MR. MANKOFF: Object to form.

A They didn't ask me to confirm anything. They asked me to test whether there was a difference in adverse event risks.

Q In the cour --

A Reported risks.

Q Pardon me. Please continue with your ...

A That's it.

Q In the course of your expert work in this case, at any time did you see any internal Bard documents that had reached the same conclusions that you had with respect to the data that you analyzed?

MR. MANKOFF: Object to form.

A Yes, more or less. So I have seen a couple

Q Let me start off with I guess a general statement to see if you agree and then we'll drill down, okay.

What impact could differential reporting between the Simon Nitinol filter and the various retrievable filters have on your analyses in this case?

A So again, it's not -- it would not have an impact on the analysis. It would have an impact potentially on the interpretation of the reporting risk ratio. So if there is differential underreporting or overreporting, then it wouldn't be appropriate to consider the reporting risk ratio as a risk ratio.

However, that differential reporting still is not problematic insofar as being able to draw some conclusion about whether the risk ratio is greater than 1 or not as I described earlier.

So there can be differential reporting, but if that differential reporting is relatively or nearly constant across a set of adverse events of -- you know, within a class of similar degree of seriousness, then, then observ -- observation of variation in the reporting risk ratios is a strong indication of a risk ratio that's greater than 1 or elevated.

Q Now, there's a difference between differential reporting and differential detection of

A Well, I would defer to their medical expertise, but that's, that's 50 percent or, you know, some large portion of that piece of information is statistical. So I would need to evaluate how they arrived at their estimate before I could agree with it or accept it.

Q What, if anything, did you do in this case to control for the possibility that individuals with asymptomatic adverse events that have retrievable filters only had those symptoms detected when the filter was removed?

MR. MANKOFF: Object to form.

A I didn't have any information to do anything about that.

Q What in -- strike, strike that.

What, if anything, did you do to control in your analyses in this case for the possibility that people with asymptomatic adverse events who have retrievable filters are more likely to get imaging follow-up than those with permanent filters? What did you do to control for that in this case?

MR. MANKOFF: Object to form.

A So again, I'd want to make the distinction between the analysis and the interpretation, and the analysis was simply the calculation based on the data

MR. MANKOFF: Object to form.

A I would describe that as interpretation.

Q The various limitations that we've been discussing today are significant in your interpretation of the reporting risk ratio as it relates to the risk ratio, right?

MR. MANKOFF: Object to form.

A Only if they're actual limitations.

Q And I think we've discussed this earlier today, but you don't purport to have the medical expertise to provide expert opinions on the various limitations between use of a Simon Nitinol filter and use of a Recovery or other removable filter in various patient populations, right?

MR. MANKOFF: Object to form.

A I'm not an medical expert in these filters.

Q You're not a medical expert in the practical limitations that might impact detection of an adverse event in a removable filter versus a permanent filter, right?

THE WITNESS: Can you restate that?

MR. BUSMAN: Sure.

Q You're not a medical expert when it comes to what might impact the differential discovery and reporting of adverse events in a removable filter

versus adverse events in a permanent filter?

A I'm not a medical expert in that.

Q Who, if anybody, provided you any guidance in this regard for your report in this case?

A In which regard?

MR. BUSMAN: Strike that.

Q You do attempt to interpret the reporting risk ratio that you calculated in terms of providing some information on an estimated risk ratio, right?

A Subject to some assumptions.

Q And that's precisely what I was talking about earlier today. Who provided you the assumptions that you used?

A The assumptions are, in my view, reasonable assumptions based on, you know, my general understanding.

Q Your assumptions are not based on any medical expertise that you have with respect to these filters, right?

A I don't have medical expertise.

Q Now, I recall in your report which we've marked as Exhibit No. 6 one of the issues was -- strike that.

What, if anything, did you do to consider the effect that litigation involving removable IVC filters

might have on the number of reports in the MAUDE database for removable filters?

A So again, I wasn't using the MAUDE database directly. I was using Bard's data which as I've said I -- my understanding is overlaps with the MAUDE database, but not necessarily entirely. So, so I'm not -- I don't know how reporting -- I, I didn't take into account potential changes in reporting.

Q Based on litigation?

A Based on litigation.

Q What, if anything, did you do in this case to take into account the fact that the Simon Nitinol, which was ten-years-old at the time that your analysis began, may have been less likely to receive reports than newer products?

MR. MANKOFF: Object to form.

A So again, I didn't have the data for that first ten years. And, I believe also that there is some value, there is value to be comparing these devices contemporaneously, so at the same time.

So if I had had the data for the first ten years, I would have used it. I would have probably done both analyses, the one starting at 2000 to align everything in calendar time when -- you know, to control for medical advance, potential medical

Q It's entirely possible that the increases over time in reporting for the removable products that you noted were related to high profile litigation connected with these products, right? That's possible?

MR. MANKOFF: Object to form.

A Anything is possible. I suppose.

Q You didn't do anything to rule out that possibility, did you?

A I don't have -- I didn't have the data to be able to do that kind of level of analysis.

Q Now, you also in addition to the analysis that we've been talking about, you did two other analyses as well, the DFMEA analysis and the testing analysis, right?

A Yes.

MR. BUSMAN: Can we go off the record?

THE VIDEOGRAPHER: The time is 2:46 p.m. We're off the record.

(Short break was taken.)

THE VIDEOGRAPHER: The time is 2:57 p.m. This the beginning of tape 4. We're back on the record.

BY MR. BUSMAN:

Q Doctor, please take a look at Exhibit 8 which is your supplemental report in this case. Do you have